



THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of:

FIKES et al.

Appl. No. 09/633,364

Filed: August 7, 2000

For: **Inducing Cellular Immune
Responses to Prostate Cancer
Antigens Using Peptide and
Nucleic Acid Compositions**

Confirmation No. 3960

Art Unit: 1642

Examiner: Rawlings, S.L.

Atty. Docket: 2060.0110001

**Reply To Restriction Requirement And
Provisional Election Of Species**

Commissioner for Patents
Washington, D.C. 20231

Sir:

In reply to the Office Action dated **January 29, 2002**, requesting an election of one group to prosecute in the above-referenced patent application, Applicants hereby provisionally elect, with traverse, the peptide VLAKELKFV (PAP.30; SEQ ID NO:6827 in Table XXIVA) as defined by the Examiner, represented by new claims 114, 117, and 121-140. This election is made without prejudice to or disclaimer of the other claims or subject matter disclosed. Applicants reserve the right to file one or more divisional applications directed to non-elected subject matter should the restriction requirement be made final. In such case, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

The Epitopes Recited in the Pending Claims

Applicants have canceled claims 1-37 and have added new claims 38-210 in the Preliminary Amendment submitted herewith, with new claims 38, 62, 91, 114, 141, 169, and

190 being independent. Applicants have reduced the number of epitopes recited in the claims from 47 to 28. Further, the 28 recited epitopes represent portions of only *two* prostate cancer antigens: prostatic acid phosphatase (PAP) and prostate specific antigen (PSA). For the convenience of the Examiner, Applicants provide, in **Table 2** (attached to the Preliminary Amendment submitted herewith), a list of each epitope recited in the pending claims and the identity, and peptide number, of the prostate cancer antigen where the epitope is found.

Further, Applicants have organized the independent claims to include epitopes having the same priority dates, to aid in examination. The filing date and application number of the application in which each epitope was first disclosed by Applicants is provided in **Table 2** (attached to the Preliminary Amendment submitted herewith).

The Restriction Requirement

Concerning the restriction requirement, Applicants note that the epitopes in Groups 1-47, and those in pending independent claims 38, 62, 91, 114, and 141, are presented in Markush Groups. MPEP section 803.02 explicitly states that

[i]f the members of the Markush Group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner *must examine all members of the Markush group* . . . even though they are directed to independent and distinct inventions.

(emphasis added). Each of the Markush groups in question only includes between two and eight epitopes. It is respectfully submitted that a Markush group of two to eight is "sufficiently few in number" such that the epitopes should be examined together in accordance with the MPEP. This is especially true since these epitopes are related as discussed in the section above and shown in Table 1. In any event, even if the Examiner

disagrees and takes the position that a group of two to eight is not "sufficiently few in number," according to the MPEP,

a Markush-type claim can include independent and distinct inventions In applications containing claims of that nature, the examiner may require a provisional *election of a single species* prior to examination on the merits should no prior art be found . . . the search of the Markush-type claim *will be extended*.

MPEP § 803.02 (emphasis added). Thus, the MPEP clearly contemplates treating independent and distinct inventions in a Markush group as species *entitled to election of species practice*. Accordingly, Applicants provide the following two assertions: (1) the epitopes recited in independent claims 38, 62, 91, 114, and 141 are sufficiently few in number to warrant examination of the entire Markush group without the need for an election of species requirement, and (2) even if a group of up to eight is deemed not sufficiently few in number to warrant examination of all eight together, Applicants are entitled to an election of species requirement in accordance with the literal language of the MPEP.

Further, Applicants point out that the Office Action did not address MPEP section 803.04, directed to nucleotide sequences. Pursuant to the notice *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996), MPEP section 803.04 holds that even when nucleotide sequences encoding different proteins are contained in an application, a reasonable number, normally ten, sequences will be examined in a single application. Applicants submit that the instant amino acid sequences constitute different fragments of two proteins, rather than numerous different proteins altogether as contemplated by section 803.04. "[N]ucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together." MPEP § 803.04. Thus, Applicants respectfully submit that the present

requirement for restriction is improper. However, even if the Examiner contends that the instant epitopes constitute different proteins within the scope of section 803.04, Applicants submit that a reasonable number of such epitopes should be examined together, and the Office Action has given no indication why the search of 28 epitopes from only two proteins is unreasonable in the present case. Thus, Applicants request examination of a reasonable number of epitopes, notwithstanding the fact that they are recited in several independent claims.

Accordingly, Applicants respectfully request that the Restriction Requirement be withdrawn so the subject matter of the pending claims can be examined together.

Election of Species

The Examiner also required an election of one antigen recited in claims 14 and 30. Applicants have canceled claims 14 and 30. Additionally, as mentioned above, the new claims recite epitopes from only two antigens. However, to be fully responsive, Applicants hereby provisionally elect the subject matter of (c) prostatic acid phosphatase (PAP), as designated by the Examiner. Claims 62-69, 71-90, 114, 117-141, 144-168, and 191-210 read on the provisionally elected species. Claims 62, 114, and 141 are "generic."

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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